

**Remarks**

Claims 1, 3 to 14 and 16 have been amended. Claims 2, 15 and 19 have been cancelled without prejudice or disclaimer and with the understanding that Applicants may pursue the subject matter encompassed by the cancelled claims in a continuation application. New claims 20 to 31 have been added.

The amendments to independent claim 1 more clearly describe Applicants' claimed invention and find support, *inter alia*, in claim 2, now cancelled, and at paragraphs [0026] and [0078] in Applicants' published specification. The amendments to the dependent claims are simply formalistic in nature and/or were made to conform to the amendments to claim 1.

New claims 20 to 26 find support, *inter alia*, at paragraph [0080] of Applicants' published application. New claims 27 and 28 find support, *inter alia*, in previously pending claims 7 and 12, respectively. New claims 29 and 30 find support, *inter alia*, in previously pending claims 12 and 13, respectively. New claim 31 finds support, *inter alia*, in previously pending claim 16. Accordingly, no prohibited new matter has been added either by amendment of the previously presented claims or through the introduction of new claims 20 to 31.

**1. Rejection under 35 U.S.C. § 102(e)**

Claims 1 to 13, 16 and 19 are rejected as allegedly anticipated by WO 02/44145 A1 ("the '145 PCT"). In asserting the '145 PCT as prior art under 102(e), the Examiner points to its international filing date of November 30, 2001 and its subsequent publication date of June 6, 2002. The Examiner asserts that claim 1 of the '145 PCT broadly encompasses the compounds of formula I as recited in Applicants' claim 1 and that claim 20 of the '145 PCT lists two species that are claimed in Applicants' claim 7. In addition, the Examiner asserts that claim 21 of the '145 PCT recites pharmaceutical formulations that encompass the compounds defined in any one of the previous claims 1 to 20. The Examiner does not explicitly assert that claim 21 anticipates Applicants' claim 16, but since claim 16 also recites a pharmaceutical formulation, Applicants will presume for the purpose of providing a rebuttal that this is the Examiner's intent. Finally, the Examiner asserts that method of treatment claim 35 of the '145 PCT allegedly anticipates Applicants' method claim 19.

Applicants point out that independent claim 1, as amended, recites a sulfonic acid addition salt in crystalline form of a compound of formula I. In contrast, because the '145 PCT does not teach sulfonic acid addition salts, no less in a crystalline form, the '145 PCT cannot anticipate Applicants' claims. Applicants therefore respectfully request that this rejection be withdrawn.

To further expedite the allowance of this application, Applicants state for the record that the presently claimed invention and the application published as the '145 PCT were, at the time the present invention was made, owned by or subject to an obligation of assignment to the same entity, thereby disqualifying the '145 PCT as prior art under 102(e) / 103(c). The corresponding U.S. National Stage of the International Application that published as the '145 PCT recently granted as U.S. Patent No. 7,129,233. While Applicants do not acknowledge that any claim pending in the present application would be rendered obvious by either the disclosure of the '145 PCT or any claim of U.S. Patent No. 7,129,233, a terminal disclaimer is being submitted herewith relative to U.S. Patent No. 7,129,233 as further discussed below in Section 2A.

## **2. Obviousness-Type Double Patenting**

### **A. Claims 1 to 10, 12 and 16**

Claims 1 to 10, 12 and 16 are rejected as allegedly unpatentable over claim 55 of Application No. 10/432,411 (now U.S. Patent No. 7,129,233).

Although Applicants do not agree with this rejection, Applicants have, in order to expedite prosecution of the subject application, submitted herewith a terminal disclaimer of the subject application over U.S. Patent No. 7,129,233. Further, because the patent term of U.S. Patent 7,129,233 is subject to a terminal disclaimer over U.S. Patent 7,056,907, Applicants have also submitted herewith a terminal disclaimer of the subject application over U.S. Patent 7,056,907.

### **B. Claim 16**

Claim 16 is provisionally rejected over claims 3 and 5 to 9 of copending Application No. 10/481,232; claims 1 to 8 of copending Application No. 10/516,423; and claims 1 to 10 of copending Application No. 10/516,420.

Although Applicants do not agree with this rejection, Applicants have, in order to expedite prosecution of the subject application, submitted herewith a terminal disclaimer of the subject application over copending Application No. 10/516,420 (now allowed). Regarding the provisional double patenting rejections over the currently unexamined Application Nos. 10/481,232 and 10/516,423, Applicants would like to remind the Examiner that if the claims in an application are otherwise in a condition for allowance, any remaining provisional obviousness-type double patenting rejections should be withdrawn and addressed in the copending applications over which the provisional rejections are made (see MPEP 804(B)(1)). In this case, Applicants believe that all other outstanding rejections have been fully addressed and that the claims in the subject application are otherwise in a condition for allowance. Applicants will address the provisional double patenting rejections of record during prosecution of the 10/481,232 and 10/516,423 applications if and when allowed claims are identified.

Applicants note for the record that under MPEP 804.02, the filing of the terminal disclaimers is not intended to be an admission that Applicants' claimed subject matter is not patentably distinct over the claimed subject matter in U.S. Patent No. 7,129,233; U.S. Patent No. 7,056,907; and U.S. Patent Application No. 10/516,420. Rather, the filing of the terminal disclaimers "simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection" (citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991)).

**3. Rejection under 35 U.S.C. § 112, first paragraph**

Method of treatment claim 19 is rejected as allegedly failing to comply with the enablement requirement. The Examiner asserts that allowance of such a claim would grant Applicants the right to exclude others from using the claimed invention to treat every disease where inhibition of thrombin is required and that there is no evidence that Applicants' claimed compositions are capable of treating such a wide variety of disorders.

Although Applicants do not agree with this rejection, Applicants have, in order to expedite prosecution of the subject application, cancelled claim 19 without prejudice or disclaimer.

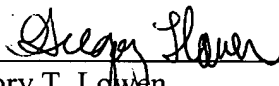
**4. Conclusion**

The foregoing amendments and remarks are being made to place the application in a condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

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Respectfully submitted  
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